AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 90

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50119C00072	See Block 20C	OS248161

5. ISSUED BY	CODE	ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. ADMINISTERED BY *(If other than Item 5)*	CODE	ASPR-BARDA

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

7. NAME AND ADDRESS OF CONTRACTOR *(No., Street, City, Country, State and ZIP Code)*

CYTOVALE INC 1535473
Attn: AJAY M SHAH
150 EXECUTIVE PARK BLVD STE 4100
SAN FRANCISCO CA 941343322

8. DELIVERY
☐ FOB ORIGIN ☒ OTHER *(See below)*

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: See G.4

CODE 1535473 FACILITY CODE

11. SHIP TO/MARK FOR	CODE	HHS/OS/ASPR

HHS/OS/ASPR
200 C St SW
WASHINGTON DC 20201

12. PAYMENT WILL BE MADE BY	CODE	PSC

PSC

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253 (c) ( )

14. ACCOUNTING AND APPROPRIATION DATA: 2019.1992019.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT: $3,407,480.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
Ajay M. Shah, President & CEO	MATTHEW A. MCCORD

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY *(Signature of person authorized to sign)*	September 28 2019	BY Matthew A. Mccord -S *(Signature of the Contracting Officer)*	28 Sept. 2019

Digitally signed by Matthew A. Mccord -S
DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2000572498, cn=Matthew A. Mccord -S
Date: 2019.09.28 15:13:46 -04'00'

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STANDARD FORM 26 (Rev. 5/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

CYTOVALE INC 1535473

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 45-4784004 DUNS Number: 078418950 Delivery: 09/30/2019 Appr. Yr.: 2019 CAN: 1992019 Object Class: 25106 Period of Performance: 09/30/2019 to 01/15/2021				
1	Performing R&D services in support of Septiscan product and manufacturing development to design freeze and design verification and validation preparation Reports and other deliverables. Obligated Amount: $3,407,480.00				3,407,480.00
2	Performing R&D services in support of the execution of SeptiScan analytical and clinical validation, and preparation for regulatory submission Reports and other deliverables. Amount: $2,915,564.00(Option Line Item)				0.00
3	Performing R&D services related to securing the SeptiScan supply chain and preparing for manufacturing scale up and validation Reports and other deliverables. Amount: $423,187.00(Option Line Item)				0.00
4	Complete Regulatory submission and obtain FDA 510(k) regulatory Clearance Reports and other deliverables. Amount: $369,888.00(Option Line Item)				0.00
5	Finalize Manufacturing Readiness for Launch. Reports and other deliverables. Amount: $467,739.00(Option Line Item)				0.00

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PART I – THE SCHEDULE

SECTION A. ABSTRACT

In 2018, the Biomedical Advanced Research and Development Authority (BARDA) established the Division of Research, Innovation, and Venture (DRIVe). The mission of DRIVe is to encourage agile business practices, accelerate biomedical innovations, and improve the availability of transformative products & technologies to proactively protect Americans from natural and intentional health security threats. The following contract and the Statement of Work (addressed in Section C), further the mission and goals of DRIVe.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract is for Research & Development Services related to the advanced development of the SeptiScan System for sepsis diagnosis that rapidly quantifies immune activation through measuring the biophysical properties of cells (termed deformability cytometry). This diagnostic will be able to aid in the early diagnosis of sepsis in patients presenting with signs or suspicion of infection in the Emergency Department with a sample to answer in <5min. The platform employs label-free microfluidic technology, ultra-high rate frame camera, with machine vision in image processing and machine learning, with minimal sample handling by the user and low consumables cost.

The Advanced Research and Development effort will progress in specific stages of a base (CLIN001) work segment and the four (4) option work segments. Work performed during the base segment and in each of the four (4) option segments constitutes independent, non-severable discrete work segments that cannot be further subdivided for separate performance. Work specified in each work segment is necessary to support product and manufacturing development to design freeze, and design verification and validation preparation (CLIN001), execute analytical and clinical validation and prepare for regulatory submission (CLIN002), secure supply chain and prepare for manufacturing scale up and validation (CLIN003), complete FDA Regulatory submission and obtain regulatory clearance (CLIN004), and finalize manufacturing readiness for launch (CLIN005).

The Government has determined that it has a Bona Fide Need for each non-severable discrete work segment. That need will be met upon the completion of the defined task(s) listed in the Statement of Work (SOW) for each work segment (See Section J-Attachment 1) and the completion of the Go/No-Go milestones. Each work segment provides independent merit and value to the Government. Each work segment will be fully funded from an appropriation source that is current at the time the contract is awarded (Base Work Segment, CLIN0001) and at the time the Government exercises each option.

B.2 BASE PERIOD

a. The title of this contract is "Advancing a biophysical early sepsis diagnostic towards FDA 510(k) clearance", BARDA-BAA-18-100-SOL-00003 (Special Instructions) (Development Area of Interest #15.1)

b. The contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 Audit Records-Negotiation (Oct 2010).

c. It is estimated that the monies currently obligated at the time of contract award will cover performance of the Base Period/CLIN0001(see chart below):

CLIN	Description	Period of Performance	Estimated Total Cost	Estimated Contractor Cost-Share (35%)	Estimated Government Cost
001	Performing R&D services in support of Septiscan product and manufacturing development to design freeze and design verification and validation preparation Reports and other deliverables.	September 30, 2019 through January 15th, 2021	$5,242,278.00	$1,834,798.00	$3,407,480.00

B.3. OPTION PERIODS

a. The contract includes 4 Option Periods:

   a. CLIN 002: Execute Analytical and Clinical Validation, and Prepare for Regulatory Submission, Period of Performance March – December 2020
   b. CLIN 003: Secure Supply Chain and Prepare for Manufacturing Scale Up and Validation Period of Performance April-October 2020
   c. CLIN 004: Complete Regulatory Submission and Obtain FDA 510(k) regulatory Clearance Period of Performance October 2020-July 2021
   d. CLIN 005: Finalize Manufacturing Readiness for Launch, Period of Performance October 2020-July 2021

b. Pursuant to FAR 52.217-9, Option to Extend the Term of the Contract (Mar 2000), set forth in full in ARTICLE I.2 of this contract, the government may, by unilateral contract modification, require the Contractor to perform discrete portions of additional work contained within CLIN 002,003,004,005 and as specified in the Statement of Work.

CLIN	Description	Period of Performance	Estimated Total Cost	Estimated Contractor Cost-Share (35%)	Estimated Government Cost
002	Performing R&D services in support of the execution of SeptiScan analytical and clinical validation, and preparation for regulatory submission Reports and other deliverables.	March 1, 2020 through March 1, 2021	$4,485,483.00	$1,569,919.00	$2,915,564.00

003	Performing R&D services related to securing the SeptiScan supply chain and preparing for manufacturing scale up and validation Reports and other deliverables.	April 1, 2020 through October 31, 2020	$651,057.00	$227,870.00	$423,187.00
004	Complete Regulatory submission and obtain FDA 510(k) regulatory Clearance Reports and other deliverables.	October 1, 2020 through July 31, 2021	$493,184.00	$123,296.00	$369,888.00
005	Finalize Manufacturing Readiness for Launch Reports and other deliverables.	October 1, 2020 through December 1st, 2021	$623,652.00	$155,913.00	$467,739.00

B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clauses (FAR 52.216-7, Allowable Cost and Payment) incorporated into the contract and unless authorized in writing by the Contracting Officer, the cost of the following items or activities shall be unallowable as direct costs at any level (i.e. including subcontracts) for:

1) No personal IT computer equipment (e.g. including but not limited to personal computers; cell phones; tablets; printers; etc.) Note: It is stipulated that the 10 SeptiScan Systems to be manufactured in the scope of this contract are authorized as direct costs.

2) Acquisition, by purchase or lease, of any interest in real property;

3) Special rearrangement or alteration of facilities;

4) Lease or purchase of any item of general purpose office furniture, office equipment, or personal computers/tablets regardless of dollar value.

5) Attendance at scientific meetings/conferences;

6) Printing Costs (as defined in the Government Printing and Binding Regulations);

7) Overtime (premium) compensation

8) Entering into certain types of subcontracting arrangements (See Section B.5(c) for specific obligations). Note that most consulting agreements require CO's

written consent.

9) No travel costs are authorized under this contract at the prime level as they were negotiated as part of Contractor's cost-share contribution.

10) Refreshment & Meal Expenditures (non-travel related)

11) Consultant Costs (see Article B.5)

12) Subcontractor costs (see Article B.5)

B.5. ADVANCE UNDERSTANDINGS

a. **Cost Sharing Arrangement**

Contractor and BARDA have agreed to enter into a cost-share contract. In addition to covering all travel related costs for activities relating to the contract, Contractor agrees to pay **35% of total costs for CLIN 001, CLIN 0002, CLIN0003, and 25% of total costs for CLIN 004, and CLIN 0005** over the life of the contract. This shall be represented by the corresponding amount (i.e.25-35%) reduction (as stated above per the respective CLIN) to the bottom line of any invoice submitted under performance of this contract.

b. **Subcontracts and Consultants**

Award of any FFP subcontract or FFP consulting agreement in excess of $250,000 or any cost reimbursement, time and materials, or labor hour subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within ten (10) calendar days of full execution.

c. **Person-in-Plant**

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility, who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor or subcontractor plant.

d. **Quality Assurance (QA) Audits**

BARDA reserves the right to participate in QA audits of the Contractor (excluding Contractor's internal audits) and Contractor's audit of the vendors for GxP compliance, as well as 3rd party audits of vendors when related to performance under the contract. Upon

completion of the QA audit, the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and COR for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of regular communications.
- Contractor shall notify the CO and COR within 5 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings.

e. **Overtime Compensation**

No overtime (premium) compensation is authorized under the subject contract.

f. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial information outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

g. **Approval of Clinical Protocols**

The Contractor shall submit all clinical protocols and informed consent documents as referenced under this Contract to the COR for review and approval **prior** to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government shall try to review all submitted documents promptly within ten (10) business days of submission. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any clinical protocol.

h. **In-Process Review (IPR)**

At its discretion, the Government may conduct an In-Process-Review (IPR) to evaluate whether to continue activities covered by the contract. Contractor shall provide a presentation detailing technical progress made towards completion of milestones following

a prescribed template provided by the Government at an agreed upon date. The IPR will typically be conducted at DHHS facilities in Washington, DC. The contractor will be notified by the Government of its intention to hold an IPR at least 30 calendar days prior to the scheduled IPR Presentation.

Contractor shall provide final presentation 10 business days prior to each IPR Presentation. Contractor shall submit written justification of progress towards satisfying success criteria. The Government will provide written or verbal comments, as appropriate, if the Contractor provides a draft prior to a submitting a final presentation.

B.6 508 Compliance

The Contractor will be expected to comply with Section 508 requirements on any electronic document submitted to HHS during the period of performance that is intended for public dissemination by either the contractor or HHS or is necessary for proper deployment/use of the product (Clinical Trial protocols, Consent Forms, Investigator's Brochure, etc.).

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

See Attachment 1 (Statement of Work) as agreed upon by the Government and Contractor.

C.2 REGULATORY ACTIVITIES

The Contractor shall submit to the COR for review and comment, pre-submission documents, submission documents, results documents, and all proposed regulatory filing documents with the FDA.

C.3 QUALITY

The Contractor may be required to establish and maintain a Quality Management System for the proposed effort with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to establish routine internal reviews of the proposed effort with documentation and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to subcontract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D – PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: https://www.acquisition.gov/FAR/ . HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

FAR Clause **Title and Date**

FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection and acceptance will be take place at a location designated by the Contracting Officer or at:

Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
O'Neill House Office Building
Washington, DC 20515

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including, under mutually agreed conditions, collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within ten (10) business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the Base Period in Section B.2. If the government exercises option(s) the period of performance will be extended as described under Section B of the contract.

F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in Attachment 1 of this contract and upon delivery and acceptance, as required by the Attachment 1 (SOW), attachment 2 (Deliverables) and Attachment 3 (Go/No Go decisions), by the COR, and of each of the deliverables described in Section C and Section F below.

All deliverables and reporting documents listed within this Section shall be delivered electronically to the CO, CS, and the COR as well as in the designated eRoom along with an email unless otherwise specified by the CO.

	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award. There will be a teleconference kickoff meeting focused on the contract and a face to face kick-off meeting that will be focused on the technical components of this contract	• Contract kickoff Within 15 days of contract award. • Technical Face to Face kickoff within 3 months. • Contractor shall provide itinerary and agenda at least 2 business days in advance of meeting. • Contractor provides meeting minutes to COR within 5 business days after the meeting. • COR reviews, comments, and approves minutes within 10 business days.
02	Monthly Teleconference	The Contractor shall participate in monthly teleconferences with BARDA to discuss the performance of the contract.	• Contractor provides agenda and slides 24 hrs in advance of the meeting

	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates
			• meeting minutes to COR within 7 business days of the meeting
2.1	Face to Face Project Meetings	The contractor shall hold face to face meeting for program review as designated by the COR. These meetings will be used to discuss contract progress in relation to the program management deliverables described in this contract and SOW as well as study designs, regulatory and manufacturing updates.	• Contractor shall provide itinerary at least 7 days in advance of the meeting. • Slides provided 24 hrs in advance • Meeting minutes due 7 days after the meeting
03	Monthly Technical Progress Reports	Describing project progress over the previous month.	• Monthly Reports shall be submitted on the 15th day of the month after the end of each month. Monthly progress reports are not required for the periods when the Final Report is due. The COR and CO will review the monthly reports with the Contractor and provide feedback . • In the technical progress report, the contractor shall provide key data and/or specific analysis of data generated with contract funding. Additional data shall be provided as requested.
04	Publications	Any manuscript, scientific meeting abstract, scientific presentation or press release containing data generated under this contract or referencing the technical work performed under this contract must be submitted to BARDA for review prior to submission	• Contractor must submit all manuscript or scientific meeting abstract to PO and CO for review at least 15 calendar days for manuscripts and 5 calendar days for abstracts

	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates
			• Contractor must address in writing all concerns raised by BARDA • Final submissions shall be submitted to BARDA concurrently or no later than one (1) calendar day of its submission
05	Final Data Submission Package	Contractor must submit a data package consisting of all analyses produced under this contract and, at the request of the Government, supporting raw data. Data may be used by DRIVe for analysis, evaluation, constistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	• Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
06	Draft Final Report and Final Report	These reports are to include a summation of the work performed and results obtained for the entire contract period of performance and shall be in sufficient detail to describe comprehensively the results achieved. The reports shall include the following sections: Cover Page, Executive Summary and Results. The Draft Final Report will be submitted to the Contracting Officer's Representative and CO who will review the Draft Final Report and provide the Contractor with comments. The Final Report shall include or address the COR's and CO's written comments on the draft report. Note: There will be one Final Report due at the end of the Base Period and one Final Report encompassing the entire contract due upon completion of the Option Period, if exercised.	• The Contractor shall submit the Draft Final Report to the COR and CO 30 calendar days prior to contract end date, who will review and provide the Contractor with comments. The Final Report shall include or address the COR's and CO's written comments on the draft report. • The Contractor will deliver the final version of the Final Report on or before the completion date of the contract.

	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates

a. **Periodic Document Review**

The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the Government. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA in writing.

b. **Deliverables Arising from FDA Correspondence**

1) FDA Meetings

i. The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings as silent observers. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

ii. Contractor shall notify BARDA of upcoming FDA meetings within 24 hours of scheduling.

iii. The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

2) FDA Submissions

i. The Contractor shall provide BARDA the opportunity to review and comment upon all documents submitted to the FDA or other regulatory agency. In addition an electronic copy of the final FDA submissions will also need to be submitted. All documents shall be duly marked as either "Draft" or "Final."

1. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt. This review may be done in parallel with final review by Contractor's Executive Management so long as BARDA is notified of any material changes prior to submission.

2. If BARDA reviews draft documents, the Contractor shall address BARDA's written concerns and/or recommendations prior to FDA submission. The final decision maker on content submitted to FDA is the Contractor.

3. Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar days of their submission to FDA.

3) FDA Audits

i. In the event of an FDA inspection of Contractor's facilities which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. Only content not related to work under this contract should be redacted. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

ii. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt.

iii. If BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

1. Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.

2. Contractor shall provide redacted copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.

3. Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

4. The final decision maker on content is the Contractor.

Final FDA submissions shall be submitted to the CO and COR.

4) Other FDA Correspondence

The Contractor shall forward to the CO and COR any substantive correspondence between Contractor and FDA as related to activities funded under this contract within 5 business days. All documents shall be duly marked as either "Draft" or "Final."

c. **Reporting and Meeting Details Specifics**

1) Monthly Progress Report
This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I - An introduction covering the purpose and scope of the contract effort;
SECTION II – PROGRESS
SECTION II Part A: OVERALL PROGRESS - A description of overall progress;
SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes);

SECTION II Part C: TECHNICAL PROGRESS - For each activity related to the Gantt chart, document the results of work completed. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. Include progress or status updates for all SOW tasks in each of the monthly technical progress reports for which there is activity ongoing in that SOW task area(s) as well as data for completed studies in any SOW task.
The report shall also include a description of notable problems encountered and proposed corrective action; notable differences between planned and actual progress, why the differences have occurred and what corrective actions are planned;

SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next reporting period and preprints/reprints of papers and abstracts, and a current/updated Gantt chart.

SECTION II Part E: Outstanding Issues/Anticipated Areas of Concern - a list of any existing contractual concerns that impact the technical scope of work, schedule, or pricing, as well as a list of potential or anticipated areas of concern that may be encountered in the future months.
A Monthly Progress Report will not be required in the same month that the Annual or Final Reports are submitted.

Final Report(s)Requirement
This report shall include a summation of the activities during the CLIN.

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I-EXECUTIVE SUMMARY - A brief overview of the work completed and major accomplishments achieved during the reporting period.

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS - A description of overall progress highlighting the significant accomplishments in the past year;
SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes

SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. The report should summarize progress made under each SOW task

2) Monthly Calls
A conference call between the Contracting Officer's Representative (COR) and the Contractor's Project Leaders/delegates and designees shall occur monthly or as directed by the Contracting Officer and Contracting Officer's Representative. During this call the Contractor's Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects as this may be requested by the Contracting Officer's Representative.

3) Project Meetings
The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings (kick-off meetings, project reviews, etc) with BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract, the Contractor will provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer and Contracting Officer's Representative in order to facilitate review of contract activities provided, however, that any disclosures to outside USG and USG contractors/consultants

will be subject to appropriate non-disclosure agreements.

Electronic copies of the conference call meeting minutes/summaries by the Contractor shall be provided via e-mail to the CO and COR by the Contractor within five (5) business days after the conference call is held. The COR will review these minutes for approval within 15 business days

d. **Experimental Protocols**

Notwithstanding guidance found under Article H in this document related to clinical protocols, the Contractor shall submit all formal analytical performance validation and stability testing study designs and protocols to BARDA for review and comment before proceeding with the studies. Additional study designs and experimental protocols shall be shared as requested by BARDA.

F.3 SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

SECTION G - CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following Contracting Officers (CO) will represent the Government for the purpose of this contract:

Matthew A. McCord
Contracting Officer
HHS/ASPR/AMCG
O'Neill House Office Building
Washington, DC 20515
202-510-5716(Office)
matthew.mccord@hhs.gov

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.
4) The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

Dr. Kimberly Sciarretta
COR
HHS/ASPR/BARDA
O'Neill House Office Building
Washington, DC 20515
202-603-5728
Kimberly.Sciarretta@hhs.gov

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
3) Performing technical evaluation as required;

4) Performing technical inspections and acceptances required by this contract; and
5) Assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
Henry Tse, PhD	CTO (PI)
Tiffany Vo	Sr. Manager for Business Strategy (PM)
Ajay Shah, PhD	CEO
Jennifer Beedon	COO
Laurence Ruiz-Taylor, PhD	Sr. Director, IVD Program Management

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications (CV, etc) of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

G.4. INVOICING

a. Invoices will be submitted each **30 days**. Invoices shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th day after the close of the reporting period. The line entries for subdivisions of work (CLINs) and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through H, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This

clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under Section J entitled, "Financial Report of Individual Project/Contract,".

f. Invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent to the following points of contact. Additionally, Contractor may be required to submit to a DRIVe specific invoice tracking system as will be directed by the CO.

CO	COR	PSC
Matthew A. McCord Contracting Officer matthew.mccord@hhs.gov	Kimberly Sciarretta COR Kimberly.Sciarretta@hhs.gov	PSC_Invoices@psc.hhs.gov

The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the total estimated costs for the Base Period (See estimated costs under Section B) and Options, once awarded and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states:

LIMITATION OF COST (APR 1984)

(a) The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

(b) The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that -

(1) The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

(2) The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

(c) As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

(d) Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause -

(1) The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and

(2) The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii)provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

(e) No notice, communication, or representation in any form other than that specified in subparagraph (d)(2) above, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

(f) If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

(g) Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

(h) If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

h. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

i. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in Section F.3 ELECTRONIC SUBMISSION) and an e-mail notification of the upload will be provided to the CO and COR.

j. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Oct 2008).

k. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown for items over $1000.
5. Travel – N/A under this award
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount.
9. Other Direct Costs - Include detailed breakdown for items over $1000 when total amount is over $5,000.
10. G&A / Indirect Rate - Cite rate and amount (if applicable)
11. Total Cost (illustrating applicable cost-share)

Note: Subcontracts that are cost-reimbursement in nature must also provide similar breakouts in order to enable the USG to review and confirm costs are allocable, allowable, and reasonable.

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

G.6. INDIRECT COST RATES

The following Contractor established provisional billing rates are incorporated into the contract, and will be utilized for billing purposes during the Base Period (CLIN 0001) and total estimated cost. See FAR clause 52.216-7.

Rate Type	**Rate**	**Allocation Base**
G&A - Provisional	40%	Direct Labor, Fringe, Overhead, and Other Direct Costs

The following Indirect Cost Ceilings are established for the Base Period (CLIN 0001) and total estimated cost plus Option Periods ONLY if exercised by the CO. The Contractor cannot seek reimbursement in excess of the following Indirect Rate Ceilings:

Rate Type	**Rate**	**Allocation Base**
G&A - Ceiling	50%	Direct Labor, Fringe, Overhead, and Other Direct Costs

Use of the above provisional rates does not change any cost ceilings, contract obligations, or specific allowance or disallowance provided for in the contract.

Final rate proposals must be sent to the CO & cognizant government auditor, within 6 months subsequent to the fiscal year end. (See also FAR Clause 52.216-7 incorporated herein).

G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number from Page 1 of the contract.

G.9. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this contract, the Contractor shall comply with the following and consistent with FAR guidance . The Contractor shall submit the report annually, titled "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee.

Title will vest in the Government for property purchased as a direct cost. Upon completion of the contract disposition of property will be determined by the Contracting Officer of record pursuant to FAR property regulations.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.2 PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.3 IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other such data determined by DHHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.4 EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

H.5 CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification

shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.6 INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest.

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest

managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.7 NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.8 DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.9 CONFIDENTIALITY OF INFORMATION

[Reserved]

H.10 ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.11 [Reserved]

H.12ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

Except for necessary releases to subcontractors and advisors, and in connection with regulatory reporting requirements or other releases to partners and potential partners, no information related to data obtained under this contract shall be released or publicized without providing BARDA with at least fifteen (15) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract.
Any publication containing data generated under this contract must be submitted for BARDA review no less than fifteen (15) calendar days for manuscripts and five (5) calendar days for abstracts
before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. _____."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced

Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures under Contract No. _____."

H.13 Contractor Use of the Powered by DRIVe Logo

1) For the limited purposes of the Contractor's participation related to the subject DRIVe contract, Contractor is permitted to use the following logo (the "Logo") for the period of the Term (or for a longer period, if agreed between the Parties), subject to the Contractor's full performance of the terms and conditions of the subject contract and provided that Contractor shall cease to use the Logo immediately upon BARDA's request.

2) The Contractor's use of the term "Powered by DRIVe" shall be subject to DRIVe Brand Guidelines.

3) Any other use of the DRIVe name, its Logo, servicemarks or trademarks, or any of its other distinguishable marks, whether registered or not, shall be limited to those granted by the express, written permission of the BARDA. Those to whom such permission is granted must agree that BARDA shall remain the final arbiter of the use of the mark or Logo.

a. BARDA Use of Contractor Logo

Contractor hereby grants BARDA/DRIVe the right to use Contractor's corporate logo (and other artwork as agreed to by the Parties), for presentations, internal and external websites, and other reasonable promotional and reporting uses relating to the Project during the Term (or for a longer period, if agreed between the Parties).

H.14 PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007- title45-vol1/CFR-2007-title45-vol1-part5b

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200.

H.15 LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

H.16 QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits of the Contractor (except for Contractor's internal audits) and Contractor's audit of the vendors for GxP compliance, as well as 3rd party audits of vendors when related to performance under the contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of regular communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.17 BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.18 RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien'

with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.19 NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within 2 business days of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 10 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

H.20 [Reserved]

H.21 DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical articles for which the contractor can assert a copyright under FAR Clause 52.227-14 (c) no information related to data obtained under this contract shall be publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical article, the contractor shall provide BARDA, through the COR, with a minimum of fifteen (15) business days to review the article prior to publication.

H.22 REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these

funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/

H.23 MANUFACTURING STANDARDS

Except as set forth in the Statement of Work, The Good Manufacturing Practice Regulations (GMP) (21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.24 LABORATORY LICENSE REQUIREMENTS

The contractor shall comply with all applicable requirements of the Code of Federal Regulations Title 21, Part 58 and FDA Medical Device GMP Guidance. This requirement shall also be included in any subcontract for services under the contract.

H.25 SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, will be incorporated herein by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at

http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.26 PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

H.27. [RESERVED]

H.28 CLINICAL TERMS OF AWARD

In addition to those terms and conditions outlined under applicable HHSAR clauses incorporated by reference by Section I of this contract, the following clinical terms of award detail an agreement between the BARDA and the Contractor; they apply to all contracts involving clinical research.

Draft protocols for each clinical study will be submitted to BARDA for evaluation and comment. BARDA comments will be addressed and/or incorporated into the draft protocol prior to submission to the FDA for comment, if required.

BARDA shall have rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

Important information regarding performing human subject research is available here and should be addressed by the contractor. https://www.hhs.gov/ohrp/

Any updates to clinical studies (enrollment, technical results, etc) are to be addressed in the Monthly and Final Reports, as well as technical monthly calls. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

At the time of award, Contractor represents that the proposed clinical studies are minimal risk, and based on review of FDA communications, IDE exempt, and therefore excluded from the requirements in sections i(b), iii, and iv below. Contractor agrees to immediately notify BARDA if IDE-exempt status changes.

i. Safety and Monitoring Issues

a. Institutional Review Board or Independent Ethics Committee Approval

The Contractor must submit to BARDA a copy of IRB-or IEC-approved informed consent documents, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. Contractor must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify BARDA through the COR or CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

b. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany

the Contractor on site visits and/or audits of CROs as BARDA deems necessary. The Contractor shall inform BARDA 30 days in advance of a DSMB board meetings for studies funded under this effort. BARDA reserves the right to participate in the DSMB board meetings on an impromptu basis as a non-voting member, if feasible per the structure of the study. If not, the communications from the DSMB to the Contractor should be made available to BARDA upon receipt.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made by the Contractor, based on FDA and BARDA guidance, before enrollment starts, if applicable. Discussions with the responsible BARDA PO regarding appropriate safety monitoring must take place, and the Contractor must submit a written response to all concerns raised by BARDA, before patient enrollment begins and may include discussions about the appointment of one of the following:

Independent Safety Monitor – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.

Data and Safety Monitoring Board – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. BARDA should be provided documentation from DSMB and should be provided with any decisions by Contractor regarding the DMSB as it relates to work under this contract.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to BARDA before enrollment starts. If concerns are raised, Contractor must address all concerns to BARDA, in writing, before enrollment begins. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with BARDA.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

ii. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent form/document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to BARDA) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from BARDA in accordance with this section of this contract.

iii. Investigational New Drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted.

The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold other than costs that are associated with activities related to patients coming off study, monitoring, or ending the study.. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

iv. Required Time-Sensitive Notification

a. Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA representative or the Contracting Officer's Representative (COR) as follows:

- Expedited safety report of unexpected or life-threatening experience or death. A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports of serious and unexpected adverse experiences. A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 day after the IND sponsor's receipt of the information, must be submitted to the BARDA representative or COR within 24 hours of FDA notification.

- IDE reports of unanticipated adverse device effect. A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports. Sent to BARDA representative or the COR concurrently with the report to FDA.

- Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

b. Safety reporting for research not performed under an IND or IDE:

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the BARDA PO or the COR and the Contractor.

In case of problems or issues the COR will contact the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

c. Human Material (Assurance of OHRP Compliance).

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by Contractor.

Provision by the Contractor to the CO of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

H.29. FOREIGN TRANSFER OF ASSETS OR TECHNOLOGY

This clause shall remain in effect during the term of the Contract.

a. Definitions

AFFILIATES: Associated business concerns, non-profit organizations, or individuals if, directly or indirectly, (1) either one controls or can control the other; or (2) a third party controls or can control both.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government ("USG") and Contactor in this Contract.

TECHNOLOGY: Technical Data, Computer Software, manufactured materials and Subject Inventions funded by the USG under this Contract. Technology also includes contractor *know how* and personnel expertise, as well as other Assets necessary to assure successful completion of this Contract.

FOREIGN FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of a country other than the United States of America (U.S.), its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

U.S. FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of the United States, its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of the USG; and firms, institutions or business organizations which are owned or substantially controlled by U.S. citizens, firms, institutions, governmental agencies or individuals.

b. General

The Parties agree that research findings and technological developments made under this Contract constitute an investment by the USG on behalf of its citizens in the interest of their economic and national health security. These investments are made for the primary benefit of the citizenry of the U.S. with those same benefits potentially accruing to the people of all nations. Therefore, the USG has a fiduciary responsibility to protect the full invested value of the Assets and Technology developed under this Contract. The USG is also cognizant of the duty the Contractor has to its shareholders and other stakeholders with a vested interested in the economic success of the Contractor. At times both parties are aware their respective interests may diverge. Therefore, in the course of conducting business though the Contract, access to technology developments under this Contract by Foreign Firms or Institutions must be carefully considered.

c. Export Controls

Contractor agrees to comply with all applicable laws regarding export controls and not to export any Asset or Technology to any U.S. embargoed countries.

d. Post-award Transfer of Ownership of Assets or Technology

The Contractor shall provide notice to the Contracting Officer and COR within three (3) business days of any discussions of a proposed transfer of ownership or establishment of a licensing agreement of any Asset or Technology funded under this Contract from the Contractor to a Foreign Firm or Institution. Notice will also be given within three (3) business days of any discussions of a proposed transfer of operational, corporate, or economic control of Assets and Technology funded under this Contract to Foreign Firms or Institutions. For purposes of this Article, discussions are defined as the date on which the Contractor receives a "term sheet" (or similar document related to a prospective deal related to the aforementioned actions), or learns a relevant term sheet is being prepared, whichever occurs first. This Article shall not apply to transfers by the Contractor to Affiliated entities of the Contractor, as well as technology transfers for the purposes of manufacturing in accordance with the Statement of Work.

Prior to transferring any Asset funded by the USG under this Contract, the Contractor should carefully review the USG rights under FAR Subpart 42.12 pertaining to Novation, specifically FAR section 42.1204. That provision provides that the USG may recognize a third party assignment only if the transfer of Assets and Technology is determined to be in the USG's interests. The Contractor should be aware that the USG is under **no** obligation to recognize a successor in interest. If the Contracting Officer determines that a transfer of Assets and Technology may have adverse consequences to the economic well-being or national health security interests of the U.S., the Contractor, and the Contracting Officer shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which may provide substantially equivalent benefits to the Contractor.

In addition to the USG licensing rights to subject inventions and technical data funded under this Contract, see FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor) and FAR Clause 52.227-14 (Rights in Data - General), the USG shall have a first right of refusal for the purchase of the Asset and/or Technology funded under the Contract. The USG may waive this first right of refusal in writing submitted to the Contractor within ninety (90) calendar days of the initial notification to the USG of the

Contractor's intent to conduct any form of Asset or corporate transfer.

Except for transfers to affiliates of the Contractor, including those entities necessary to complete the Statement of Work, the Contractor shall provide written notice to the Contracting Officer and COR of the scheduled transfer to a Foreign Firm or Institution at least ninety (90) calendar days prior to the scheduled date of transfer. Such notice shall cite this Article and shall specifically identify the Asset or Technology proposed for the transfer and the general terms of the transfer. **No transfer shall take place without written concurrence from the Contracting Officer.**

e. Transfer to a Prohibited Source

In the event of a transfer of an Asset and/or Technology by the Contractor to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to Federal Acquisition Regulation Subpart 25.7: (a) the Government may terminate this contract for cause and (b) the license rights to the technical data and subject invention under the relevant FAR IP Clauses (FAR Clause 52.227-11 and FAR Clause 52-227-14) shall survive the termination. Upon request of the USG, the Contractor shall provide written confirmation of such licenses.

f. Lower Tier Agreements

The Contractor shall include this Article as necessary and suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier. Unless Contracting Officer objects in writing, the Contractor will determine which lower tier agreements require inclusion of this Article as the ultimate responsibility for compliance with this Article remain with Contractor .

PART II - CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Cost-Sharing Research and Development (R&D) Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-10	Oct 2018	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-18	Jul 2015	Commercial and Government Entity Code Maintenance
FAR	52.204-23	Jul 2018	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-25	Aug 2019	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Oct 201 8	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations

FAR	52.210-1	Apr 2011	Market Research
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data —Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-12	Apr 1988	Cost Sharing Contract
FAR	52.217-9	Mar 2000	Option to Extend the Term of the Contract
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Representation
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
FAR	52.222-25	Apr 1984	Affirmative Action Compliance
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Jan 2019	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Aug 2018	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement

FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General
FAR	52.227-14 Alt. II	Dec 2007	Rights in Data - General - Limited Rights Notice
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer–System for Award Management
FAR	52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.242-15	Aug 1989	Stop Work Order
FAR	52.242-15 Alt. I	Aug 1989	Stop Work Order
FAR	52.243-2	Aug 1987	Changes – Cost-Reimbursement Alternate V (Apr 1984)
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Jan 2019	Subcontracts for Commercial Items
FAR	52.245-1	Jan 2017	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

Reg	Clause	Date	Clause Title
HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2015	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation (included in full text below)
HHSAR	352.233-70	Dec 2015	Choice of Law (Overseas)

HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-6	Dec 2015	Restriction on Use of Human Subjects.
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience
HHSAR	352.270-13	Dec 2015	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 5 days of end of period of performance.

FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)

a. The Government may exercise the options outlined in this contract by mutual agreement of the parties.
b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

FAR Clause 52.219-28, Post-Award Small Business Program Representation (July 2013)

a. *Definitions* . As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business,

number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall re-represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of this re-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the

representation was completed:

The Contractor represents that it [x] is, **[] is not** a small business concern under NAICS Code 54171 assigned to this contract. [54171 NAICS Code]

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--

"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

I.2. ADDITIONAL HHSAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

HHSAR 352.231-70 – Salary Rate Limitation (December 18, 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management website for Federal Executive Schedule salary levels.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated 12 September 2019

2. Deliverables Table

3. Go/No Go Decision Table

4. Contract budget, dated 17 September 2019

5. Sample Invoice/Financial Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Sharing Contracts

6. Report of Government Owned, Contractor Held Property

   Located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

1) Human Subjects Assurance Identification Numbers: To be provided prior to study execution for each subcontractor and/or clinical site

   Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

End of Contract

Attachment 1

Statement of Work – 12 September 2019

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

Biomedical Advanced Research and Development Authority (BARDA)
Special Instruction under DRIVe Broad Agency Announcement

Project Title: Development of the SeptiScan Program

A. STATEMENT OF WORK

PREAMBLE

Independently, and not as an agent of the government, Cytovale shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to complete the product development of the SeptiScan Program and seek regulatory clearance for the SeptiScan System.

The scope of work for this contract includes product, manufacturing and supply chain development of the SeptiScan instrument modules, accessories, and consumables, analytical and clinical design validation of the SeptiScan System performance on production equivalent units in multi-site studies, preparation of the FDA 510(k) pre-market submission package for submission and anticipated regulatory clearance, and launch preparations including manufacturing process validation at commercial scale.

The scope of work is broken into the following 5 CLIN phases:

- CLIN 1: Product and Manufacturing Development to Design Freeze, and Design Verification and Validation Preparation
- CLIN 2: Execute Analytical and Clinical Validation, and Prepare for Regulatory Submission
- CLIN 3: Secure Supply Chain and Prepare for Manufacturing Scale Up and Validation
- CLIN 4: Complete Regulatory Submission and Obtain FDA 510(k) Regulatory Clearance
- CLIN 5: Finalize Manufacturing Readiness for Launch

CLIN 1: PRODUCT AND MANUFACTURING DEVELOPMENT TO DESIGN FREEZE, AND DESIGN VERIFICATION AND VALIDATION PREPARATION

CLIN 1 is in support of the Development Stage Gate. The completion of all the AIMs and associated deliverables in this CLIN are required to formally exit the development stage and support design verification and validation activities. Briefly, AIM 1 is focused on design documentation to capture decisions made about the design with respect to requirements. In AIM 2, the focus is on the final generalization testing of the classification SeptiScan Algorithm and locking the SeptiScan Algorithm for the validation study and obtaining feedback on the user interface. In AIM 3, the transfer of the design to manufacturing is initiated to generate production equivalent units. The delivery of production equivalent systems and consumables to Cytovale will serve as an approval trigger for CLIN2 (CLIN2 Go/No-go Milestones). Subsequently, the Design Freeze and Development Stage Gate Review minutes, with accompanying design review materials (i.e. approval materials documenting the readiness of the SeptiScan System to enter the Design Verification Stage), will serve as one of the approval go/no-go Milestone for CLIN 3 (CLIN 3 Go/No-Go Milestone #1). Finally AIM 4 will focus on preparing for the execution of the design verification and validation activities; the aim will focus on reaching engineering and clinical operation readiness to enroll and execute the analytical performance and clinical validation studies that will be the focus of CLIN2. First IRB approvals obtained for the analytical validation and clinical validation studies will serve as a third approval go/no-go Milestone for CLIN2 (CLIN 2 Go/No-Go Milestone #3). The end of AIM 4 will be demarcated by a Clinical Readiness Review which will provide the decision to start enrollment and will serve as the second approval go/no-go Milestone for CLIN3 (CLIN 3 Go/No-Go Milestone #3).

Proposed Period of Performance: September 2019 – January 2021

AIM 1: Complete Engineering Design Optimization of the SeptiScan System and Freeze Requirements

This aim seeks to integrate the learnings from the Beta Clinical Study and implement necessary design improvements for the SeptiScan System modules, software, and consumables (i.e. reagents, controls, and cartridge). The improved system design, its usability, and performance, including preliminary short-term reagent stability studies, will be assessed against target specifications through non-clinical and clinical engineering studies ahead of design freeze, on prototypes and production equivalent units. These studies will be executed in Cytovale's facilities in San Francisco (healthy donors and nonclinical studies) and Baton Rouge (studies involving clinical samples as well as nonclinical samples).

Objective: Demonstrate SeptiScan System design engineering readiness and lock design input requirements ahead of design freeze – AIM 1 is performed concurrently with AIMs 2, 3 and 4.

AIM 1 Tasks/WBS:

1.1 Program Management (WBS 1.1) – supports all AIMS in CLIN 1

1.1.1 Technical and Contractual Project Management (WBS 1.1.1).

- The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;
- A principal investigator (PI) or project manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors. The

contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

- A project manager with responsibility for monitoring and tracking day-to- day progress and timelines; coordinating communication and project activities; costs incurred; and program management. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;
- A BARDA liaison with responsibility for effective communication with the Contracting Officer (CO) and Contracting Officer's Representative (COR). The liaison may be the PM;
- Administrative and legal staff capability with responsibility for developing compliant subcontracts, consulting, and other legal agreements; ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights; and reporting all inventions made in the performance of the contract;
- Administrative staff capability with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors;
- Contract Review Meetings:
  - The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO and COR. Such meetings may include, but are not limited to, meeting of the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the contractor;
  - The contractor shall participate in teleconferences every month with the CO and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.
- Gantt Chart
  - Within 30 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO and COR for review and comment. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance of the contract. The contractor shall include the key milestones and Go/No-Go Milestones.
  - Project Management Plan: In the management of this contract, the contractor shall utilize Project Progress Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes. The contractor shall submit the project progress management report to the CO and COR on a monthly basis.
- Monthly Reports: *If requested, the contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW, or other Project Management Plan tool(s):*
  i. Executive summary highlighting the progress, issues, and relevant manufacturing, engineering/non-clinical, clinical, and regulatory activities;
  ii. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
  iii. Updated Risk Management Plan (every three months);
  iv. Three-month rolling forecast of planned activities;
  v. Progress of regulatory submissions

1.1.2 Risk Management (WBS 1.1.2)

Develop a Risk Management Plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans. This plan should reference

relevant WBS elements where appropriate. Updates to this plan shall be included, at a minimum, on a quarterly basis (every three months) in the monthly Project Status Report.

1.1.3 Subcontractors Management (WBS 1.1.3)
Manage subcontractors and consultants providing specific contracted services informing the development of, or manufacturing materials for the SeptiScan program for the timely completion of program deliverables.

1.1.4 Data Management (WBS 1.1.4)

i. Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;
ii. Provide for the statistical design and analysis of data resulting from the research; and
iii. Provide raw data or specific analyses of data generated with contract funding to the CO and COR, upon request.
iv. Prepare journal and conference publications in support of dissemination of key program findings.

1.2 Engineering (WBS 1.2)

1.2.1 SeptiScan Instrument System Development (WBS 1.2.1)
Complete the design improvements and development of the SeptiScan System instrument modules (SPM, CYM, IAM modules) hardware, software, and packaging.

1.2.2 SeptiScan Consumables Development (WBS 1.2.2)
Complete the development of SeptiScan System Consumables (cartridges, reagents, external controls, sample prep tube), including primary and secondary packaging labeling.

1.2.3 Engineering non-clinical studies (WBS 1.2.3)
Design hardware and software pre-verification activities and human factor evaluations assessing hardware, software engineering readiness and usability of the SeptiScan System instrument and modules.

1.7 Quality Assurance (WBS 1.7) – supports all AIMS in CLIN 1

1.7.1 Quality Management (WBS 1.7.1)
Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

1.7.2 Subcontractors Compliance Management (WBS 1.7.2)
Qualify and manage vendors' related quality processes, audit critical vendors per audit schedule.

AIM 2: Freeze SeptiScan System Algorithm and Confirm Suitability of System User Interface.

This aim seeks to initiate a naïve study site (b)(4) to test and lock the SeptiScan Algorithm prior to evaluating patients in the formal Clinical Validation Study, where a parallel objective is to test and provide feedback on the SeptiScan System user interface with intended users in an intended environment. In support of these objectives, we are proposing to collect and process up to (b)(4) samples at a naïve clinical laboratory site operated by non-Cytovale intended users / laboratory operators using the SeptiScan intended user Graphical User Interface (GUI) workflow. This additional testing will provide insights into the generalization of the SeptiScan Algorithm and offer a chance to get direct feedback from intended users on the SeptiScan System user interface as they operate the instrument to process the samples. User feedback will be collected through a survey . Results will be compared to our released user needs document (REQ-0001). Any changes will be incorporated in GUI designs prior to the design freeze. The SeptiScan and adjudication results from

this naïve site study will be reviewed to assess performance prior to freezing algorithm parameters, performance metrics, and cutoffs as part of the formal Design Freeze process.

Objective: Finalize and document the SeptiScan Algorithm and obtain intended user feedback on the System user interface.

AIM 2 Tasks/WBS:

1.1. Program Management (WBS 1.1) – supports all AIMS in CLIN 1

Program management scope in AIM 2 is consistent with program management scope in AIM 1.

1.3 Data Management & Biostatistics (WBS 1.3)

1.3.1 Algorithm / Diagnostic Model Development (WBS 1.3.1)

Perform data analysis and pre-verification of algorithm parameters and report performance obtained from the non-clinical engineering studies and naïve clinical site study, as wells as performance metrics and proposed cut offs for the clinical validation study.

1.4 Clinical (WBS 1.4)

1.4.1 Naïve Clinical Site Study (WBS 1.4.1)

Clinical operations to support enrollment at a naïve clinical site for collection and processing of up to (b)(4) samples using the intended use workflow in support of assessing instrument user interface, user feedback, and clinical operation logistics.

1.7 Quality Assurance (WBS 1.7) – supports all AIMS in CLIN 1

1.7.1 Quality Management (WBS 1.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

1.7.2 Subcontractors Compliance Management (WBS 1.7.2)

Qualify and manage vendors' related quality processes, audit critical vendors per audit schedule.

AIM 3: Transfer Design and Manufacture Production Equivalent Investigational Use Only Instruments and Consumables

This aim focuses on initiating the transfer of the design to contract manufacturers and locking the requirements before building and evaluating the first pre-production instruments and consumables at low volume scale. These Investigational Use Only (IUO) pilot instruments and consumable lots will be used under AIM 1 to assess the maturity of the overall design (including hardware, software, and user interface) ahead of design freeze. In parallel, we will begin securing the product supply chain by negotiating contract manufacturing services, supply agreements, and quality agreements with key vendors.

Objective: To build and evaluate the production equivalent SeptiScan instruments and consumables pilot lots ahead of design freeze and work towards securing the SeptiScan supply chain.

AIM 3 Tasks/WBS:

1.1 Program Management (WBS 1.1) – supports all AIMS in CLIN 1

Program management scope in AIM 3 is consistent with program management scope in AIM 1.

1.5 Manufacturing Operations (WBS 1.5)

1.5.1 Contract Manufacturer (CM) Production Equivalent IUO SeptiScan Instrument Manufacturing (WBS 1.5.1)

Transfer the SeptiScan Instrument and modules design to the CM, develop and manage the associated instrument supply chain, develop the manufacturing assembly, test procedures and acceptance criteria and build up to 10 Investigational Use Only (IUO) production equivalent SeptiScan units.

1.5.2 CM Production Equivalent IUO SeptiScan Consumables Manufacturing (WBS 1.5.2)

Transfer the SeptiScan consumables (cartridge, reagents, controls, packaging) design to contract manufacturers, develop and manage the associated supply chain, develop the manufacturing assembly, test procedures and acceptance criteria for the production equivalent lots. Build and release production equivalent IUO SeptiScan Consumable lots of cartridges (minimum of 500 units per lot), reagents (minimum of 50 units per lot), and external controls (minimum of 50 units per lot).

1.7 Quality Assurance (WBS 1.7) – supports all AIMS in CLIN 1

1.7.1 Quality Management (WBS 1.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

1.7.3 Subcontractors Compliance Management (WBS 1.7.2)

Qualify and manage vendors' related quality processes, audit critical vendors per audit schedule.

AIM 4: Readiness to enroll FPI for Analytical Performance Validation Studies & Clinical Validation Studies

This aim seeks to complete the preparations for formal device engineering design verification, analytical performance validation and clinical validation testing, and ready the clinical sites for First Patient In (FPI). Activities will include preparing analytical and clinical validation plans and protocols per FDA pre-submission feedback (Q160124 #S002), qualifying and contracting clinical and laboratory sites, designing study protocols in support of analytical performance studies and clinical validation studies, submitting all relevant protocols and Informed Consent Forms for IRB approvals, preparing all studies documentation and binders, completing site initiation visits, systems installation, and training of operators at the clinical labs that will be executing the analytical performance validation studies, and completing at least one site initiation visit, system installation and training of operators at one of the clinical labs that will be executing the clinical validation study. At the end of this aim, a Clinical Operations Readiness Review will be held to demonstrate readiness to enroll in the analytical and clinical validation studies.

Objectives: Complete all necessary activities to allow for formal design engineering verification studies execution and start of enrollment to support analytical performance and clinical validation studies.

AIM 4 Tasks/WBS:

1.1 Program Management (WBS 1.1) – supports all AIMS in CLIN 1

Program management scope in AIM 4 is consistent with program management scope in AIM 1.

1.2 Engineering (WBS 1.2)

1.2.4 Prepare for design verification and validation (WBS 1.2.4)

Develop verification and validation plans, engineering verification protocols (HW, SW), analytical performance study protocols, test methods work instructions, validate tools and test methods, prepare user training documentation.

1.2.5 Field Engineering (WBS 1.2.5)

SeptiScan System installation and qualifications at the clinical laboratory sites, laboratory operators training, instrument services and repairs, preventive maintenance.

1.3 Data Management & Biostatistics (WBS 1.3)

1.3.2 Prepare for design verification and validation (WBS 1.3.2)

Develop processes and plans for data management, monitoring, statistical analyses; develop study databases; develop analytical performance study protocols, test methods work instructions, validate tools (including electronic data capture tools) and test methods as applicable.

1.4 Clinical (WBS 1.4)

1.4.2 Prepare for analytical performance, healthy reference range, and clinical validation studies (WBS 1.4.2)

Identification of clinical sites and clinical laboratories for enrolling and executing the analytical, healthy reference range and clinical validation studies, contracting the selected sites, develop the study protocols and ICFs for the Analytical Validation, the Healthy Reference Range and Clinical Validation Studies, seeking IRB approval for the different study protocols, preparing the clinical data management plan, qualifying sites executing the studies, developing study binders, and completing site initiation visits.

1.6 Regulatory (WBS 1.6)

1.6.1 Update Regulatory Strategy (WBS 1.6.1)

Review and update the regulatory strategy of the SeptiScan System as needed based on FDA feedback obtained at the Q160124 S001 and S002 pre-submission meetings or other input changes.

1.6.2 FDA Communications (WBS 1.6.2)

i. Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication, including submitting pre-submission supplements as needed.
ii. Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages; and
iii. Provide BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA, and (ii) final draft minutes of any informal meeting with the FDA.

1.6.3 Labeling (WBS 1.6.3)

Prepare Investigational Use Only - Instruction for Use, Package Insert and User Manual documentation per 21CFR809.10(b) for use on the analytical, healthy reference range, and clinical validation studies.

1.7 Quality Assurance (WBS 1.7) – supports all AIMS in CLIN 1

1.7.1 Quality Management (WBS 1.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

1.7.4 Subcontractors Compliance Management (WBS 1.7.2)
Qualify and manage vendors' related quality processes, audit critical vendors per audit schedule.

CLIN 2: EXECUTE ANALYTICAL & CLINICAL VALIDATION, AND PREPARE FOR REGULATORY SUBMISSION

CLIN 2 will focus on the execution of design verification, analytical validation and clinical validation activities. It will also focus the preparing the 510(k) regulatory study package as data becomes available. The initiation of CLIN 2 will be dependent upon the successful completion of the approval go/no go milestone(s) in CLIN 1.

Proposed Period of Performance: March 2020 – March 2021

AIM 5: Execute Engineering Design Verification and Analytical Performance Studies
This aim seeks to execute and complete the formal engineering design verification and analytical performance validation for the SeptiScan System on GMP production equivalent units and consumables. It will focus on the execution of system and modules design verification activities, initiation of long-term stability studies for reagent and cartridge consumables (per CLSI EP25 guidance), and execution of analytical validation studies per the study design discussed and agreed upon with FDA. Due to their specific design, analytical validation studies will be executed concurrently to the clinical validation studies described in AIMs 6 and 7. This aim will also support the execution of all the studies through study materials inventory management (i.e. manufacturing of additional consumable lots as needed and shipping to study sites).

Objective: Complete SeptiScan formal design verification, analytical validation and interim long-term stability testing to use in FDA 510(k) submission.

AIM 5 Tasks/WBS:

2.1 Program Management (WBS 2.1) – supports all AIMS in CLIN 2
Program management scope in CLIN 2 - AIM 5 is consistent with program management scope in CLIN 1 - AIM 1.

2.2 Engineering (WBS 2.2)

2.2.1 Execute components and system modules engineering design verification (WBS 2.2.1)
Execute component and system modules engineering design verification and validation per approved verification protocols and prepare reports.

2.2.2 Execute SeptiScan System analytical performance studies (WBS 2.2.2)
Execute the SeptiScan System analytical performance validation and stability studies per their approved protocols and prepare reports.

2.2.3 Field Engineering (WBS 2.2.3)
All remaining SeptiScan System installation and qualifications at the clinical laboratory sites, laboratory operators training, instrument services and repairs, preventive maintenance.

2.3 Data Management & Biostatistics (WBS 2.3)

2.3.1 Execute Data Analysis (WBS 2.3.1)
In support of analytical performance studies, healthy reference range study, and clinical validation study: monitor data, perform analyses, aggregate data points per study, evaluate

statistical acceptance criteria, report key findings and construct tables as per primary and secondary objectives.

2.4 Clinical (WBS 2.4)

2.4.1 Execute Analytical Performance Validation, Healthy Reference Range, and Clinical Validation Studies (WBS 2.4.1)

Initiate enrollment for the Analytical Performance Validation, Healthy Reference Range, and Clinical Validation Studies; communicate with sites to maintain commitment to enrollment and data quality, provide regular updates and monitor sites for compliance as planned. Manage study material inventory to sites. Manage the Trial Master Files (TMF). Manage adjudication process. Support the verification and lock of the study databases and prepare clinical analyses.

2.5 Manufacturing Operations (WBS 2.5)

2.5.1 CM Production Equivalent IUO SeptiScan Consumables Manufacturing (WBS 2.5.1)

Transfer the SeptiScan consumables (cartridge, reagents, controls, packaging) design to contract manufacturers, develop and manage the associated supply chain, develop the manufacturing assembly, test procedures and acceptance criteria for the production equivalent lots. Build and release production equivalent IUO SeptiScan Consumable lots of cartridges (minimum of 500 units per lot), reagents (minimum of 50 units per lot), and external controls (minimum of 50 units per lot).

2.7 Quality Assurance (WBS 2.7) – supports all AIMS in CLIN 2

2.7.1 Quality Management (WBS 2.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

2.7.2 Subcontractor Compliance Management (WBS 2.7.2)

Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

AIM 6: Execute Healthy Reference Range Study

This aim seeks to execute the SeptiScan System Healthy Reference Range Study. This study will enroll between (b)(4) healthy subjects donating blood at (b)(4) geographically diverse locations with close proximity to a lab where the assays can be performed. Healthy subjects will span the demographic groups (e.g., age, race, ethnicity, and gender) found in the clinical validation study (AIM 7). Subjects will be analyzed as a cohort and results will be summarized. Key activities under this aim include initiating the Healthy Reference Range study at qualified sites, monitoring data, and completing enrollment. Successful completion of this phase will be marked by the release of the reference range study report.

Objective: Complete the Healthy Reference Range Study for use in the FDA 510(k) submission.

AIM 6 Tasks/WBS:

2.1 Program Management (WBS 2.1) – supports all AIMS in CLIN 2

Program management scope in CLIN 2 - AIM 6 is consistent with program management scope in CLIN 1 - AIM 1.

2.2 Engineering (WBS 2.2)

2.2.3 Field Engineering (WBS 2.2.3)

All remaining SeptiScan System installation and qualifications at the clinical laboratory sites, laboratory operators training, instrument services and repairs, preventive maintenance.

2.3 Data Management & Biostatistics (WBS 2.3)

2.3.1 Execute Data Analysis (WBS 2.3.1)

In support of analytical performance studies, healthy reference range study, and clinical validation study: monitor data, perform analyses, aggregate data points per study, evaluate statistical acceptance criteria, report key findings and construct tables as per primary and secondary objectives.

2.4 Clinical (WBS 2.4)

2.4.1 Execute Analytical Performance Validation, Healthy Reference Range, and Clinical Validation Studies (WBS 2.4.1)

Initiate enrollment for the Analytical Performance Validation, Healthy Reference Range, and Clinical Validation Studies; communicate with sites to maintain commitment to enrollment and data quality, provide regular updates and monitor sites for compliance as planned. Manage the Trial Master Files (TMF). Manage adjudication process. Support the verification and lock of the study databases and prepare clinical analyses.

2.7 Quality Assurance (WBS 2.7) – supports all AIMS in CLIN 2

2.7.2 Quality Management (WBS 2.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

2.7.2 Subcontractor Compliance Management (WBS 2.7.2)

Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

AIM 7: Execute Clinical Validation Study

This aim seeks to execute the SeptiScan System formal Design Clinical Validation Study, for which acceptance criteria have already been discussed with FDA. Key activities include initiating the clinical study at qualified sites, monitoring data, commencing and completing enrollment of multi-site, multi-hundred patient clinical study (3-5 sites, up to 750 patients) to achieve our primary and secondary study objectives. Successful completion of this phase will be marked by the release of the clinical validation final analysis for 510(k) filing.

Objective: Complete the multi-site SeptiScan Clinical Validation Study for use in the FDA 510(k) submission.

AIM 7 Tasks/WBS:

2.1 Program Management (WBS 2.1) – supports all AIMS in CLIN 2

Program management scope in CLIN 2 - AIM 7 is consistent with program management scope in CLIN 1 - AIM 1.

2.2 Engineering (WBS 2.2)

2.2.3 Field Engineering (WBS 2.2.3)

All remaining SeptiScan System installation and qualifications at the clinical laboratory sites, laboratory operators training, instrument services and repairs, preventive maintenance.

2.3 Data Management & Biostatistics (WBS 2.3)

2.3.1 Execute Data Analysis (WBS 2.3.1)

In support of analytical performance studies, healthy reference range study, and clinical validation study: monitor data, perform analyses, aggregate data points per study, evaluate statistical acceptance criteria, report key findings and construct tables as per primary and secondary objectives.

2.4 Clinical (WBS 2.4)

2.4.1 Execute Analytical Performance Validation, Healthy Reference Range, and Clinical Validation Studies (WBS 2.4.1)

Initiate enrollment for the Analytical Performance Validation, Healthy Reference Range, and Clinical Validation Studies; communicate with sites to maintain commitment to enrollment and data quality, provide regular updates and monitor sites for compliance as planned. Manage the Trial Master Files (TMF). Manage adjudication process. Support the verification and lock of the study databases and prepare clinical analyses.

2.7 Quality Assurance (WBS 2.7) – supports all AIMS in CLIN 2

2.7.1 Quality Management (WBS 2.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

2.7.2 Subcontractor Compliance Management (WBS 2.7.2)

Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

AIM 8: Prepare for FDA 510(k) submission

This aim seeks to start the assembly of the necessary data and information collected under AIMS 5, 6 and 7 to prepare the SeptiScan 510(k) pre-market notification for timely submission to the FDA. An Interim regulatory review will assess that the package assembly is on track for submission at the end of 2020.

It will also include preparing materials for any additional pre-submission supplements deemed necessary post communications with FDA on Q160124 S001 and S002 and requesting, scheduling, and participating in all meetings with the FDA.

Objective: Start preparation of SeptiScan 510(k) pre-market notification.

AIM 8 Tasks/WBS:

2.1 Program Management (WBS 2.1) – supports all AIMS in CLIN 2

Program management scope in CLIN 2 - AIM 8 is consistent with program management scope in CLIN 1 - AIM 1.

2.6 Regulatory (WBS 2.6)

2.6.1 FDA Communications (WBS 2.6.1)

i. Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication, including submitting pre-submission supplements as needed.
ii. Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages; and
iii. Provide BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA, and (ii) final draft minutes of any informal meeting with the FDA.

2.6.2 Labeling (WBS 2.6.2)

Updated labeling with study data and draft claims for use in the regulatory submission.

2.6.3 510(k) Submission Package assembly (WBS 2.6.3)

Prepare the regulatory 510(k) pre-market notification package and lead the regulatory submission interim review to ensure submission is on track.

2.7 Quality Assurance (WBS 2.7) – supports all AIMS in CLIN 2

2.7.1 Quality Management (WBS 2.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

2.7.2 Subcontractor Compliance Management (WBS 2.7.2)

Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

CLIN 3: SECURE SUPPLY CHAIN AND PREPARE FOR MANUFACTURING SCALE UP AND VALIDATION

The initiation of CLIN 3 will be dependent upon the successful completion and approval of the go/no go milestones in CLIN 1 and CLIN 2.

Proposed Period of Performance: April 2020 - October 2020

AIM 9: Secure Supply Chain and Initiate GMP Manufacturing Scale Up

This aim seeks to continue and secure the product supply chain activities initiated under AIM 1 by negotiating contract manufacturing services, supply agreements, and quality agreements with selected key vendors, initiate the technical development of backup suppliers for critical components, initiate the planning and development of manufacturing scale up processes, process validation and plan for transfer to production.

Objective: Start securing supply chain for the SeptiScan product through a combination of agreements negotiations, development of backup suppliers and ensuring all CM partners will be able to manufacture product at the anticipated commercial scale.

AIM 9 Tasks/WBS:

3.1 Program Management (WBS 3.1)

Program management scope in CLIN 3 - AIM 9 is consistent with program management scope in CLIN 1 - AIM 1.

3.2 Engineering (WBS 3.2)

3.2.1 Secure supply chain (WBS 3.2.1)

Develop supply agreements and quality agreements with existing suppliers of critical components.

3.2.2 Technical development of backup suppliers of critical components (WBS 3.2.2)
Develop and qualify backup suppliers for critical components or subassemblies to reduce risks to the commercial supply chain.

3.2.3 Support manufacturing process scale up, validation, and transfer to production (WBS 3.2.3)
Provide oversight and technical expertise to CMs for the preparation of manufacturing process scale up, validation, and transfer to production.

3.3 Data Management & Biostatistics (WBS 3.3) - Reserved

3.4 Clinical (WBS 3.4) - Reserved

3.5 Manufacturing Operations (WBS 3.5)

3.5.1 CM manufacturing process scale up initiation, validation, and preparation for transfer to production (WBS 3.5.1)
CMs planning and initiation of manufacturing process scale up, validation, and planning for transfer to production.

3.6 Regulatory (WBS 3.6) – Reserved

3.7 Quality Assurance (WBS 3.7)

3.7.1 Quality Management (WBS 3.7.1)
Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

3.7.2 Subcontractor Compliance Management (WBS 3.7.2)
Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

CLIN 4: COMPLETE REGULATORY SUBMISSION AND OBTAIN 510(k) REGULATORY CLEARANCE

The initiation of CLIN 4 will be dependent upon the successful completion and approval of the Go/No Go milestones in CLIN 2.

Proposed Period of Performance: October 2020 – July 2021

AIM 10: Obtain 510(k) Regulatory Clearance

This aim focuses on finalizing the 510(k) package for submission to FDA and thereafter on the 510(k) review process and timely engagement with FDA to address any questions arising in relation to our regulatory submission. It will also include establishing consumables' expiration dates from real-time stability testing negotiating final claims, intended use/indication for use statement, and labeling with the Agency. It will also include preparing materials, requesting, scheduling, and participating in all meetings with the FDA.

Objective: Finalize, submit the 510(k) pre-market notification and support the 510(k) regulatory review process to obtain regulatory clearance.

AIM 10 Tasks/WBS:

4.1 Program Management (WBS 4.1)
Program management scope in CLIN 4 - AIM 10 is consistent with program management scope in CLIN 1 - AIM 1.

4.2 Engineering (WBS 4.2)

4.2.1 Complete stability studies for components expiration dating (WBS 4.2.1)
Complete on-going long term and any stability studies initiated under AIM 5 on consumables (reagents and cartridge) to enable shelf-life dating claims in the labeling.

4.3 Data Management & Biostatistics (WBS 4.3) - Reserved

4.4 Clinical (WBS 4.4)

4.4.1 Conduct clinical site close out visits (WBS 4.4.1)
Conduct clinical sites and laboratory sites close out visits.

4.5 Manufacturing Operations (WBS 4.5) - Reserved

4.6 Regulatory (WBS 4.6)

4.6.1 FDA communications (WBS 4.6.1)

i. Address the Food and Drug Administration (FDA) questions as they arise during the review process in a timely manner to support the use of the product for the specific indication and obtention of regulatory clearance letter;
ii. Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages; and
iii. Provide BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA, and (ii) final draft minutes of any informal meeting with the FDA.

4.6.2 510(k) Submission Package final assembly and transmittal (WBS 4.6.2)
Finalize the regulatory 510(k) pre-market notification package for submission and submit.

4.6.3 Labeling (WBS 4.6.3)
Finalize Instruction for Use, Package Insert and User Manual documentation per 21CFR809.10(b) for the final product in agreement with FDA.

4.7 Quality Assurance (WBS 4.7)

4.7.1 Quality Management (WBS 4.7.1)
Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

4.7.2 Subcontractor Compliance Management (WBS 4.7.2)
Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

CLIN 5: FINALIZE MANUFACTURING READINESS FOR LAUNCH

The initiation of CLIN 5 will be dependent upon the successful completion and approval of the go/no go milestones in CLIN 2 and CLIN 3.

Proposed Period of Performance: October 2020 – December 2021

AIM 11: Readiness for Launch

This aim will be initiated post completion of AIM 9 and seeks to complete the design transfer, GMP manufacturing scale up, and process validation of the SeptiScan System and consumables. Other activities in preparation for launch will include updating the launch and go-to-market plans, and establish customer processes *(e.g., order processing and fulfillment, technical support/complaints, servicing, recall management)* and post market surveillance.

Objective: Complete the SeptiScan System and consumables manufacturing scale up, process validation, and prepare for Launch.

AIM 11 Tasks/WBS:

5.1 Program Management (WBS 5.1)

Program management scope in CLIN 5 - AIM 11 is consistent with program management scope in CLIN 1 - AIM 1.

5.2 Engineering (WBS 5.2)

5.2.1 Secure supply chain (WBS 5.2.1)

Develop supply agreements and quality agreements with existing suppliers of critical components.

5.2.2 Technical development of backup suppliers of critical components (WBS 5.2.2)

Develop and qualify backup suppliers for critical components or subassemblies to reduce risks to the commercial supply chain.

5.2.3 Support manufacturing process scale up, validation, and transfer to production (WBS 5.2.3)

Provide oversight and technical expertise to CMs for the preparation of manufacturing process scale up, validation, and transfer to production.

5.3 Data Management & Biostatistics (WBS 5.3)

5.3.1 Prepare publications (WBS 5.3.1)

Prepare manuscripts presenting the analytical performance and clinical utility of the SeptiScan System obtained from the analytical and clinical validation pivotal studies.

5.4 Clinical (WBS 5.4) - Reserved

5.5 Manufacturing Operations (WBS 5.5)

5.5.1 CM manufacturing process scale up initiation, validation, and preparation for transfer to production (WBS 5.5.1)

CMs planning and initiation of manufacturing process scale up, validation, and planning for transfer to production.

5.5.2 Complete process validation and transfer to production (WBS 5.5.2)

CMs completion of manufacturing process scale up, validation, and transfer to production.

5.6 Regulatory (WBS 5.6) - Reserved

5.7 Quality Assurance (WBS 5.7)

5.7.1 Quality Management (WBS 5.7.1)

Manage compliance to quality system processes and procedures, approve documentation and change controls, and manage the SeptiScan System Device History File.

5.7.2 Subcontractor Compliance Management (WBS 5.7.2)

Qualify, manage vendors' related quality processes, audit critical vendors per audit schedule.

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Cytovale Inc – REVISED DRAFT PROPOSAL

Deliverables Table

Contract Period	AIM#	WBS	Milestone	Deliverable	Success Criteria	Est. Completion Date
CLIN1		1.1.1	Program Management Plan and updated GANTT	Program Management Plan and updated GANTT within 30 days of contract effective date	Executive Approval of Program Management Plan and Revised GANTT	Sep 2019
CLIN1		1.1.2	Program Risk Management Plan	Program Risk Management Plan	Executive Approval of Program Risk Management Plan	Dec-Feb 2020
CLIN1	1	1.2.1, 1.2.2, 1.2.3	Technical & Design Input Review(s) records	Cytovale approved Technical Design Review(s) and Design Input Review(s) records (e.g. review meeting minutes with any relevant accompanying review materials, including Human Factor report) documenting, respectively, the performance of the SeptiScan System and consumables post design improvements from non-clinical and clinical engineering studies, and the review of the SeptiScan System design requirements ahead of design freeze	Engineering and Quality approved Technical and Design Input Review(s) records	Monthly through Mar 2020
CLIN1	1	1.2.1, 1.2.2	Locked Design input Documentation	Released User Needs Requirements, Product Requirements, Hazards and Risk documents, and Trace Matrix.	Cytovale approved locked design documentation for system modules and consumables released to Cytovale's QMS	Mar 2020
CLIN1	2	1.4.1	User Feedback Report	Cytovale approved user feedback report summarizing user survey results against user needs requirements and informing on potential changes and improvements to the user interface.	Approval of survey results capturing user feedback including assessment of potential changes and improvements to the user interface.	Dec 2019

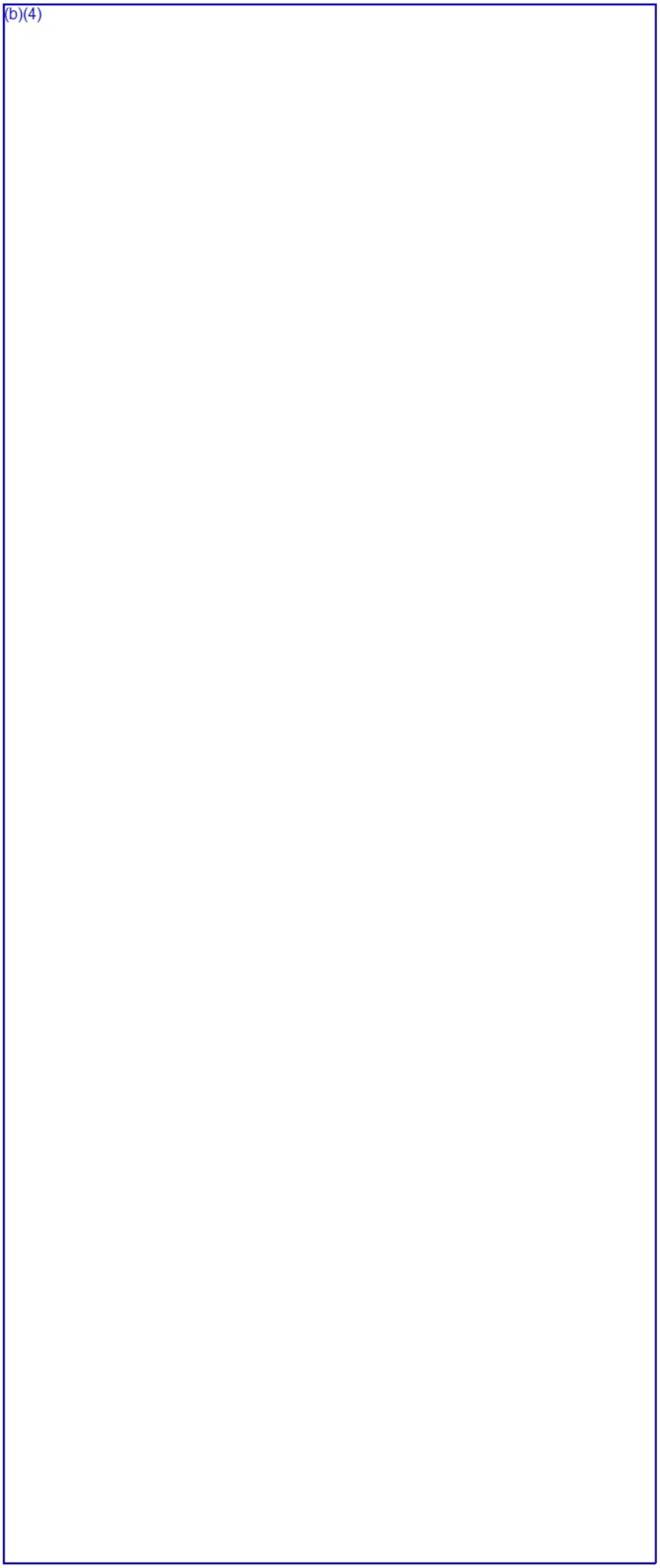
Contract Period	AIM#	WBS	Milestone	Deliverable	Success Criteria	Est. Completion Date
CLIN1	2	1.3.1	Algorithm Freeze Design Review	Cytovale approved Algorithm Design Freeze Review records (*e.g., review meeting minutes with any relevant accompanying review materials*) documenting the SeptiScan Algorithm Design Freeze, performance metrics with confidence intervals, and final cutoffs ahead of design freeze and validation	Data Science and Quality approval of frozen algorithm design	Mar 2020
CLIN1	3	1.5.1	CLIN2 approval go/no-go: Three (3) QA-Released SeptiScan Systems	Minimum of three (3) production equivalent SeptiScan Systems built and delivered to Cytovale with build and test documentation.	Delivery of three (3) SeptiScan Systems with associated documentation to Cytovale	Feb 2020
CLIN1	3	1.5.2	CLIN2 approval go/no-go: Two (2) QA-Released Consumables Lots	Minimum of two production equivalent lots of consumables (Reagents minimum of 50 units per lot and Cartridges minimum of 500 units per lot) with associated documentation released to inventory by Cytovale Quality Assurance	Quality Assurance release of two (2) lots of consumables to inventory with associated documentation.	Feb 2020
CLIN1	1,2,3	1.2.1, 1.2.2, 1.2.3, 1.3.1, 1.4.1	CLIN3 approval go/no-go: Development Stage Gate Review	Cytovale approved Development Stage Gate records (*e.g. review meeting minutes with any relevant accompanying review materials*) documenting Design Freeze, close of Development and readiness to enter the Verification and Validation stages	Cytovale Engineering and Quality approval of Development Stage Gate demonstrating readiness to enter the Verification and Validation stages	Mar 2020
CLIN1	4	1.2.4	Verification and Validation Plans	Released Verification and Validation Plans for the SeptiScan System, modules (for	Cytovale approved Verification and Validation Plans are released to Cytovale's QMS	Dec 2019

Contract Period	AIM#	WBS	Milestone	Deliverable	Success Criteria	Est. Completion Date
				hardware and software) and consumables: • Master Design V&V plan • System V&V plan • Modules V&V Plan(s) • Consumables V&V Plan(s)		
CLIN1	4	1.2.4, 1.3.2	Repeatability and Reproducibility Protocols	• Repeatability and Within Lab Precision Study protocol • Lot-to-lot Reproducibility Study of SeptiScan Cartridges protocol	Cytovale and BARDA approved Repeatability and Reproducibility protocols and released to Cytovale's QMS	Jan 2020
CLIN1	4	1.2.4, 1.3.2	Stability Testing Protocol(s)	• Patient sample stability testing protocol • Reagents and cartridges stability testing protocols	Cytovale and BARDA approved Stability Testing protocol(s) and released to Cytovale's QMS	Jan 2020
CLIN1	4	1.4.2	Healthy Reference Range Study Protocol	Healthy Reference Range Study protocol	Cytovale and BARDA approved Healthy Reference Range Study protocol and released to Cytovale's QMS	Feb 2020
CLIN1	4	1.4.2	Clinical Validation Study Protocol	Clinical Validation Study protocol	Cytovale and BARDA approved Clinical Validation Study protocol and released to Cytovale's QMS	Feb 2020
CLIN1	4	1.4.2	CLIN2 approval go/no-go: Analytical Validation Study, Healthy Reference Range, and Clinical Study Site IRB(s) and ICF(s)	At least one IRB and ICF approval received for: • Analytical Validation Studies • Healthy Reference Range Study • Clinical Validation study	IRB and ICF approvals at 1 site for: • Analytical Validation Studies clinical protocol • Healthy Reference Range Study protocol • Clinical Validation Study protocol	Feb 2020
CLIN1	4	1.3.2, 1.4.2	CLIN3 approval go/no-go: Clinical Readiness Review	Cytovale approved Clinical Readiness Review Meeting records (*e.g. minutes with any relevant accompanying review*	Cytovale Engineering, Clinical Operations, and Quality approval to enroll for Analytical and Clinical Validation Studies	Jan 2021

Contract Period	AIM#	WBS	Milestone	Deliverable	Success Criteria	Est. Completion Date
				materials), demonstrating clinical operational readiness and capturing approval to enroll for Analytical and Clinical Validation studies		
CLIN2	5	2.4	CLIN3 approval go/no-go: Records of the First Patient In (FPI) enrolled for evaluation in the Analytical Validation Studies	Records of the First Patient In (FPI) enrolled for evaluation in the Analytical Validation Studies, including clinical enrollment record and SeptiScan test result	First Patient In (FPI) enrolled and patient sample successfully processed on the SeptiScan System to provide a SeptiScan Score result.	April 2020
CLIN2	5	2.4.1, 2.5.1	CLIN5 approval go/no-go: Shipments of study materials completed	Shipping and inventory records for the study materials shipment to clinical & lab site(s) demonstrating that all study materials shipments have been completed.	All sites have been supplied with needed study materials to complete studies execution (last inventory shipment is completed)	Aug – Sept 2020
CLIN2	5	2.2.2, 2.3.1, 2.4.2	CLIN4 approval go/no-go: Three (3) Completed DRAFT Analytical Validation Reports	DRAFT Analytical Validation Reports: • Patient Sample Stability report • Cartridge lot to lot reproducibility report • Carry over report	Three (3) analytical studies execution and analysis completed, and results summarized into final DRAFT reports available for review: • Patient Sample Stability Study • Cartridge Lot to Lot Reproducibility Study, • Sample Carryover Study	Aug-Sept 2020
CLIN2	5	2.2.2, 2.3.1, 2.4.2	Final Analytical Validation Reports	Analytical Validation Reports: • Patient Sample Stability report • 3 sites repeatability study report • Cartridge lot to lot reproducibility report • Carry over report	Cytovale approved Analytical Validation reports and released to Cytovale's QMS	Sept-Dec 2020

Contract Period	AIM#	WBS	Milestone	Deliverable	Success Criteria	Est. Completion Date
				• On-board reagent stability report • Interfering substances report		
CLIN2	5	2.2.2, 2.3.1	Interim Long-Term Stability Report(s)	• Cartridge Interim Long-Term Stability Report • Reagents Interim Long-Term Stability Report(s)	Cytovale approved Interim Long-Term Stability report(s) and released to Cytovale's QMS	Dec 2020
CLIN2	6	2.3.1, 2.4.2	CLIN4 approval go/no-go: Healthy Reference Range Study Report	Healthy Reference Range Study Report	Cytovale approved Healthy Reference SeptiScan Score Range determined and report released to Cytovale's QMS	Aug-Sept 2020
CLIN2	7	2.3.1, 2.4.2	Clinical Validation Final Analysis for 510(k) filing	Cytovale approved Clinical Validation final analysis tables and figures ready for 510(k) filing	Approved formatted tables and figures from Clinical Validation final analysis ready for 510(k) filing	Dec 2020
CLIN2	8	2.6.2, 2.6.3	CLIN4 approval go/no-go: Regulatory 510(k) submission Interim Review	Cytovale approved 510(k) Submission Interim Review records (*e.g. meeting minutes with any relevant accompanying review materials*) documenting progress of submission package and availability of a subset of completed DRAFT package sections for early review	Cytovale Regulatory approval of Interim Review meeting minutes and availability of a subset of completed DRAFT package sections for early review	Aug-Sept 2020
CLIN3	9	3.2.1, 3.2.2, 3.3.3	CLIN5 approval go/no-go: Supply Chain Interim review	Cytovale approved Supply Chain Interim Review meeting records (*e.g. minutes with any relevant accompanying review materials*) documenting manufacturing scale up and validation planning status ahead of completing Design Transfer	Cytovale Engineering, Operations, and Quality Approval of Supply Chain Interim Review Meeting demonstrating manufacturing scale up and validation planning is on track ahead of completing Design Transfer by end of 2020 / Q1 of 2021.	Aug-Sept 2020

Contract Period	AIM#	WBS	Milestone	Deliverable	Success Criteria	Est. Completion Date
CLIN3	9	3.1.1	CLIN5 approval go/no-go: Launch Plan and Forecast	Cytovale approved Launch Plan and Forecast	Delivery of Launch plan and Year 1-3 revised forecast	Aug-Sept 2020
CLIN4	10	4.6.2	SeptiScan System 510(k) Pre-market notification package	Complete SeptiScan System 510(k) Pre-market notification package as submitted to FDA	510(k) package submitted & administrative acceptance letter from FDA received	Dec 2020-Jan 2021
CLIN4	10	4.2.1, 4.6.1, 4.6.3	510(k) Clearance	510(k) Clearance letter from the FDA for the SeptiScan System	FDA clearance letter received	(b)(4)
CLIN5	11	5.2.3, 5.5.1, 5.5.2	Manufacturing Transfer Technical Review Records	Cytovale approved Manufacturing Transfer Technical Review records (*e.g. review minutes with any relevant accompanying review materials*) documenting the readiness of the SeptiScan System and consumables to move to production.	SeptiScan System and consumables to move to production approval by Engineering, Manufacturing Operations and Quality.	Dec 2020
CLIN5	11	5.2.1, 5.7.2	Supply and Quality Agreements	Supply Agreements and Quality Agreements with critical qualified vendors.	Executed supply and quality agreements	Jul 2021
CLIN5	11	5.2.2, 5.2.3, 5.5.2,	Launch Readiness Review Records	Cytovale approved Launch Readiness Review records (*e.g. meeting minutes with any relevant accompanying review materials*) demonstrating the SeptiScan System is approved for launch.	SeptiScan System is approved for commercial launch.	Dec 2021


(b)(4)

SUMMARY OF DIRECT LABOR
AND FRINGE BENEFITS

Hourly Rates

Cytovale, Inc.

DRIVe Special Instructions - BARDA Broad Agency Announcment

(b)(4)

(b)(4)

SUMMARY OF MATERIALS AND SUPPLIES

DRIVe Special Instructions - BARDA Broad Agency Announcement

(b)(4)

SUMMARY OF EQUIPMENT COSTS

Cytovale, Inc.

DRIVe Special Instructions - BARDA Broad Agency Announcement

(b)(4)

SUMMARY OF Consultants

AND FRINGE BENEFITS

Hourly Rates

(b)(4)

(b)(4)

SUMMARY OF OTHER DIRECT COSTS

Cytovale, Inc.

DRIVe Special Instructions - BARDA Broad Agency Announcement

		CLIN 1			CLIN 4			
		AIM 4			AIM 10			
	ITEM	Unit Price	Unit Quantity	Subtotal	Unit Price	Unit Quantity	Subtotal	TOTAL
1	Monthly Subscription - Electronic Data Capture Systen	$3,500	15	$52,500	0.00	0	$0	$52,500
2		0.00	0	0.00		1	0	$0
3		0.00	0	0.00	0.00	0	0.00	$0
4		0.00	0	0.00	0.00	0	0.00	$0
	TOTAL =			$52,500.00			$0.00	$52,500.00

SUMMARY OF SUBCONTRACTOR COSTS

Cytovale, Inc.

DRIVe Special Instructions - BARDA Broad Agency Announcement

	CLIN 1	CLIN 1	CLIN 1	CLIN 1	CLIN 2	CLIN 2	CLIN 2	CLIN 2	CLIN 3	CLIN 4	CLIN 5	
	1	2	3	4	5	6	7	8	9	10	11	TOTAL
(b)(4)	$ 89,982	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 89,982
	37,275											37,275
			22,192									22,192
			21,000									21,000
							72,000					72,000
			22,500									22,500
		38,969										38,969
							28,500					28,500
							135,000					135,000
						26,950	28,500					55,450
							135,000					135,000
						26,950	28,500					55,450
							135,000					135,000
						26,950	28,500					55,450
							135,000					135,000
							28,500					28,500
							135,000					135,000
					25,500							25,500
					100,000							100,000
												-
	$ 127,257	$ 38,969	$ 65,692	$ -	$ 125,500	$ 80,850	$ 889,500	$ -	$ -	$ -	$ -	$ 1,327,768

Go/No-Go Decision Gating

CLIN	Go/No-Go Decision Gate Milestone	Success Criteria	Failure Criteria	Est. Go/No-Go Decision Gate Milestone Date	Est. Trigger for CLIN/ Option
CLIN1 *(AIM 3)*	Three (3) QA-Released SeptiScan Systems	Delivery of three (3) SeptiScan Systems with associated documentation to Cytovale	Fewer than 3 production equivalent SeptiScan Systems delivered to Cytovale	Feb 2020	CLIN2
CLIN1 *(AIM 3)*	Two (2) QA-Released Consumables Lots	Quality Assurance release of two (2) lots of consumables to inventory with associated documentation.	Fewer than 2 production equivalent lots of consumables (Reagents and Cartridges) QA released by Cytovale.	Feb 2020	CLIN2
CLIN1 *(AIM 4)*	Analytical Validation Study, Healthy Reference Range, and Clinical Study Site IRB(s) and ICF(s)	IRB and ICF approvals at one (1) site for: • Analytical Validation Studies clinical protocol • Reference Range Study protocol • Clinical Validation study site protocol	No IRB and ICF approval received for any of the studies	Feb 2020	CLIN2
CLIN1 *(AIM 1, AIM 2, AIM 3)*	Development Stage Gate Review	Cytovale Engineering and Quality approval of Development Stage Gate demonstrating readiness to enter the Verification and Validation stages.	Failure to complete all necessary design control deliverables to exit the Development stage and enter the Verification and Validation stages	Mar 2020	CLIN3
CLIN1 *(AIM 4)*	Clinical Readiness Review	Cytovale Engineering, Clinical Operations, and Quality approval to enroll for Analytical and Clinical Validation studies	Failure to complete all necessary clinical readiness deliverables to open enrollment for Analytical and Clinical Validation studies	Mar 2020	CLIN3
CLIN2 *(AIM 5)*	Records of the First Patient In (FPI) enrolled for evaluation in the Analytical Validation Studies	First Patient In (FPI) enrolled and patient sample successfully processed on the SeptiScan System to provide a SeptiScan Score result.	No First Patient In (FPI) data obtained	April 2020	CLIN3

CLIN	Go/No-Go Decision Gate Milestone	Success Criteria	Failure Criteria	Est. Go/No-Go Decision Gate Milestone Date	Est. Trigger for CLIN/ Option
CLIN2 *(AIM 5)*	Shipments of study materials completed	All sites have been supplied with needed study materials to complete study execution (last inventory shipment is completed).	Unable to provide study materials to supply all sites	Aug – Sept 2020	CLIN5
CLIN2 *(AIM 5)*	Three (3) Completed DRAFT Analytical Validation Reports	Three (3) analytical studies execution and analysis completed, and results summarized into final DRAFT reports available for review: • Patient Sample Stability Study, • Cartridge Lot to Lot Reproducibility Study, • Sample Carryover Study	No final DRAFT reports provided for review	Aug-Sept 2020	CLIN4
CLIN2 *(AIM 6)*	Healthy Reference Range Study report	Cytovale approved Healthy Reference SeptiScan Score Range determined and report released to Cytovale's QMS	No report provided for review	Aug-Sept 2020	CLIN4
CLIN2 *(AIM 8)*	Regulatory 510(k) submission Interim Review	Cytovale Regulatory approval of Interim Review meeting minutes and availability of a subset of completed DRAFT package sections available for early review.	No interim review meeting conducted due to lack of available materials	Aug-Sept 2020	CLIN4
CLIN3 *(AIM 9)*	Supply Chain Interim review	Cytovale Engineering, Operations, and Quality Approval of Supply Chain Interim Review Meeting demonstrating manufacturing scale up and validation planning is on track ahead of completing Design Transfer by end of 2020 / Q1 of 2021	No interim review meeting conducted due to lack of available materials	Aug-Sept 2020	CLIN5
CLIN3 *(AIM 9)*	Launch Plan and Forecast	Delivery of Launch plan and Year 1-3 revised forecast	Failure to deliver Launch plan and Year 1-3 revised forecast	Aug-Sept 2020	CLIN5

Attachment 5 – SAMPLE INVOICE REQUEST

(a) Designated Billing Office Name and Address:

DHHS/OS/ASPR/BARDA
ATTN: Contracting Officer
O'Neill House Office Building
Washington, DC 20515

(b) Contractor's Name:

_____

Contractor's Address

_____

_____

_____

Contractor's EIN: _____

Contractor's CAGE: _____

Contractor's DUNS: _____

Point of Contact Name, Title, Email, Phone:

_____

_____

_____

_____

(c) Invoice No.: _____

(d) Date Invoice Submitted: _____

(e) Contract No.: _____

(f) Current Contract Period of Performance:

_____

(g) Total Price of Contract: _____

(h) Total Fixed-Fee (if applicable): _____

(i) Invoicing Type: Three-Way Match

(j) Office of Acquisitions:

DHHS/OS/ASPR/BARDA
ATTN: Contracting Officer
O'Neill House Office Building
Washington, DC 20515

(k) Central Point of Distribution: N/A

(l) This invoicing request represents reimbursable costs for the period from:

CLIN No.	Unit	(m) Current Amount	(n) Cumulative Amount	(o) Total Contract Amount
_____	_____	_____	_____	_____

Brief description of the work/deliverable(s) being invoiced:

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____
(Name of Official) (Title)

Note: Please attach supporting documents and details as specified in the contract to support the work/deliverable(s) being invoiced

Sample Invoice/Financial Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Sharing Contracts

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is

physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(i) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(l) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(m) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The CO may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** N/A under this award.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(o) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(p) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(q) **Subtotals:** Insert the total amounts claimed for the current and cumulative periods.

(r) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(s) **Total Allowable Costs**

(t) **Contractor Cost-Share:** Include the contractor cost-shares.

(u) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the CO may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

Attachment 6 -

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:	**CONTRACT NUMBER:**
ADDRESS:	**REPORT DATE:**
ADDRESS1:	
ADDRESS2:	**FISCAL YEAR:**
CITY:	
STATE:	
ZIP:	

CLASSIFICATION	**BEGINNING OF PERIOD**		**ADJUSTMENTS**			**END OF PERIOD**	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST >=$25K							
PROPERTY UNDER CONST <$25K							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING >=$25K							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP >=$25K							
SPECIAL TEST EQUIP <$25K							
AGENCY PECULIAR >=$25K							
AGENCY PECULIAR <$25K							
MATERIAL >=$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							

SIGNED BY:			
SIGNATURE		DATE SIGNED:	
NAME PRINTED		Email	
TITLE		TELEPHONE	